



Reference guide for New Users

Hands-on Training for Velos Study-Setup Procedures

Name: _____
 Unique Name: _____
 Phone: _____

Prerequisite:

Velos 100: Introduction to Velos eResearch for UM New Users.

Learning Objective: Take advantage of the UM Velos TRAINING instance to learn Velos using a self-guided, hands-on approach. At the end of this exercise, you will have completed all of the **minimum** process steps necessary to manage a clinical trial using Velos including:

- Create a study,
- Copy a Clinical Report Forms (CRF) into the study from the Forms Library and modify it,
- Copy a patient study calendar into the study from the Calendar Library and modify it,
- Enroll registered patients into your study,
- Enter data for enrolled patients,
- Explore some reporting functions to report on the data for patient management and tracking.

This checklist is a high-level reference guide to help you sequentially work through the process steps to achieve these learning objectives. This exercise should be supplemented with additional, parallel training from the Velos Customer Corner web site and reference to the Velos Corporation User Manuals. **The successful completion of this exercise is a prerequisite for acquiring access to the UM Velos production database instance.**

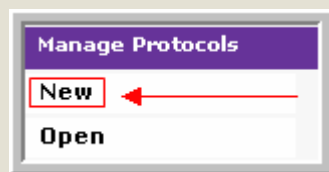
To create a report of the patient form data, contact MICHR-support@umich.edu to enroll in Velos 500: Introduction to Ad-Hoc Queries an e-learning course

Please fax the last page of this document to: **734-998-7546, Attention: MICHR CRIC Operational Support**



1. Create a study in the UM Velos training database. Use your Unique Name as study number.

A. Logon to Velos training database, click Manage Protocols → New



Check mark/Date of Completion
Comments/ Notes

B. Enter data for all mandatory fields (depicted by *) in the Study Summary tab. Enter your e-signature and click on the 'Submit' button at the bottom of the Study Summary data entry screen to save your data.

Avoid
 Selecting
 yourself as
 the Principal
 Investigator
 for this study.
 Note,
 Principal
 Investigator is
 NOT a
 mandatory
 field.

Check mark/Date of Completion
Comments/ Notes

C. On the left menu bar, navigate to the Velos homepage and notice the presence of your study record. Use the 'S' icon to access Study Administration area of your study.

Study Number	Study Title	Study Status
kwilson1	kwilson study	Not Active

Check mark/Date of Completion
Comments/ Notes

D. Click on the 'S' icon and navigate to the **Study Team** tab. Notice that Velos has automatically added you to the study team as Data Manager. Click on the 'Access Rights' link to discover the full range of privileges to the study data afforded the Data Manager Role. To maintain your full rights to your study, do not change your role on the study team.

OPTIONAL:

Practice adding study team members and assigning roles to your study team by clicking on the 'Add/Edit Study Team Members' link. Adding study team members allows other users to see your study from their Velos homepage and access your study data.

To learn more about adding study team members, assigning roles and access rights to study data, please consult the *Velos User Manual* and query on 'Study Team Tab.'

To learn more about Study Access Rights, refer to 'HH10—Study Access Rights Table' in the *Velos User Manual*.

Organization	User Name	Role	Access Rights	Status
University of Michigan	@ Kay Wilson	Data Manager	Access Rights	Active

Check mark/Date of Completion
Comments/ Notes

2. Define basic study setup infrastructure by establishing the adverse event dictionary (if needed), method of patient study ID generation, and patient enrollment process for your study.

A. Navigate to the **Study Setup** tab, and then click on [VIEW/EDIT DICTIONARIES AND SETTINGS](#) link.

Type	Use
Adverse Event Dictionary	NCI v3.0
Patient Study ID Generation	manual

Check mark/Date of Completion
Comments/ Notes

B. In the Dictionaries and Settings window, choose the AE dictionary, method of Patient Study ID generation (select manual), and the study enrollment process (as shown). Submit the data by entering your valid e-Signature to save your data.

Associate Adverse Event Dictionary

Adverse Event Dictionary	Use
Free Text Entry	<input type="radio"/>
NCI v2.0	<input type="radio"/>
NCI v3.0	<input checked="" type="radio"/>

Patient Study ID Generation

Type	Use
Allow Manual Entry	<input checked="" type="radio"/>
System-Generated sequential	<input type="radio"/>

Select an Option - Select an Option - #####

Study Enrollment Process

Enable Study-centric enrollment ☐ Yes ☒ No

Flag to Allow Patient Accrual ☒ Default ☐ Organization Specific

On submission of study-centric enrollment page, user is taken to Select an Option

e-Signature * **Submit**

Check mark/Date of Completion
Comments/ Notes



3. Develop Patient Case Report Forms for data entry in your study. (For this exercise, copy a 'blank' form from the library into your study, then add fields to it.)

Copy a form from the Form Library and edit the form:

A. Start by copying a "blank" form into your study from the library. From the Study Setup Tab, click on ["SELECT A FORM FROM YOUR LIBRARY"](#) link.

Summary Versions Admin Schedule **Study Setup** Notifications Study Status Reports Study Team Broadcast Forms

Study Number: kwilson1

Study Dictionaries/Settings

If no modifications have been specified, the default settings will be applied. [VIEW/EDIT DICTIONARIES AND SETTINGS](#)

Type	Use
Adverse Event Dictionary	Free Text Entry
Patient Study ID Generation	manual

Study Treatment Arm

Treatment Arms currently associated with this study are: [ADD NEW](#)

Name	Description
------	-------------

Associated Calendars

Calendars currently associated with this study are: [UPDATE MULTIPLE SCHEDULES](#) [COPY AN EXISTING CALENDAR](#) [SELECT A CALENDAR FROM YOUR LIBRARY](#)

Name	Refresh Notifications	Description	Status	Status Details	Reports	Delete	Save to Library
------	-----------------------	-------------	--------	----------------	---------	--------	-----------------

Associated Forms

Forms currently associated with this study are: [DISPLAY AND SEQUENCING OPTIONS](#) [SELECT A FORM FROM YOUR LIBRARY](#)

Name	Description	Linked To	Status	Preview	Delete	Info	Save to Library
------	-------------	-----------	--------	---------	--------	------	-----------------

Check mark/Date of Completion
Comments/ Notes

B. Enter 'Blank' into 'Form Name' field, click on the 'Search' button, select the blank form, and click on the downward arrow.

Search a Form

Form Name Form Type Study **Search**

The following are the Forms currently listed in your Library. Select the Form that you wish to associate with your Study or go to the Form Library to create a new Form. [CREATE A NEW FORM](#)

Select	Name	Form Type	Description	Status
<input type="checkbox"/>	Blank Form for Training	TRAINING	-	Work In Progress
<input checked="" type="checkbox"/>	Blank	TRAINING	This is a blank form to pull into studies.	Work In Progress

Forms to be Linked

Deselect	Name	Description	Display Form Link	Characteristic	Filters
----------	------	-------------	-------------------	----------------	---------

e-Signature * **Submit**
Click once only

Check mark/Date of Completion
Comments/ Notes

C. Scroll to the bottom of the screen and select the appropriate radio buttons for **Display Form Link** and **Characteristics**.

- Choose the '**patient-level**' option,
- Choose the '**once-only editable**' option.

Enter your e-Signature, and click on the 'Submit button' to copy this blank form into your study from the library.

Deselect	Name	Description	Display Form Link	Characteristic	Filters
<input type="checkbox"/>	Blank	This is a blank form to p	<input type="radio"/> Study <input checked="" type="radio"/> Patient	<input type="radio"/> Multiple entry <input checked="" type="radio"/> Only once (Editable)	Organization Select Group Select

e-Signature * **Submit**
Click once only

Check mark/Date of Completion
Comments/ Notes

D. Under the 'Study Setup' tab, under 'Associated Forms' notice the existence of the form you just pulled into your study. Note the status is work in progress and that the form is linked to the patient level.

Name	Description	Linked To	Status	Preview	Delete	Info	Save to Library
Blank	This is a blank form to pull into studies.	Patient	Work In Progress II				

Click on the blank form link to begin developing the form in your study.

Check mark/Date of Completion
Comments/ Notes

E. Start by renaming your form (optional: you may also designate if an e-Signature is required for data entry).

Define the Form | Add Fields | Form Settings

Form Name: Blank (Preview)

Form Name *

Form Description

Form Status *

☒ e-Signature is Mandatory for this form's responses

e-Signature * **Submit**
Click once only

[Back to the Study Setup page](#)

Check mark/Date of Completion
Comments/ Notes

F. Then, navigate to the 'Add Fields' tab where you will see various form development tools across the top of the screen and the form elements listed below in table format.

Sequence	Field Name	Field ID	Field Type	Modify	Delete
Section 1					
Repeat Fields:0 Format: Non-Tabular					
(1)	Data Entry Date	er_def_date_01	Edit	Modify	

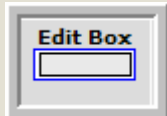
[Back to the Study Setup page](#)

Note that the blank form comes with a single date field (required in all Velos forms) to capture the data entry date. This field can be (and is in this case) set to default to the current date. In addition to this Velos required date field, we recommend creating a second date field to capture the date of visit.

Check mark/Date of Completion
Comments/ Notes

G. Add a Visit Date Field to your form:

1. Click on the Edit Box tool :



2. In the subsequent screen that pops up, select Date for 'Edit Box Type.' Then fill out the details of your new date field as shown below. (Note: you can add and rename sections to your form as well as change the sequence of each field.) All mandatory fields designated with * must be completed. Other details such as field validations and help text can be completed at your discretion.

A screenshot of the 'FIELD TYPE: EDIT BOX' configuration screen. The screen is divided into several sections. The top section contains fields for 'Section' (set to 'Section 1'), 'Sequence' (set to '2'), 'Field Name' (set to 'Date of Visit'), and 'Field ID' (set to 'VISIT_DT'). Below these are radio buttons for 'Edit Box Type' (Text, Number, Date, with 'Date' selected), 'Field Characteristics' (Visible, Hide, Disable, Read Only, with 'Visible' selected), 'Label Display Width' (a percentage field, Expand Label, Hide Label, Bold, Italics), 'Field Description', 'Search Keyword(s)', and 'Field Help (On Mouse Over)'. The bottom section is titled 'FIELD VALIDATIONS' and includes checkboxes for 'Mandatory' and 'Override Mandatory Validation'. It also has sub-sections for 'For Text Box/Number Field' (Field Length, Number of Lines, Maximum Characters/Numbers, Default Response), 'For Date Field' (Date cannot be a future date, Override Date validation, Default date to current date), and 'For Number Field' (Override Number Format Validation, Response Should Be, Override Number Range Validation). At the bottom, there is an 'e-Signature' field and a 'Submit' button with the text 'Click once only' below it. Red arrows point to various fields and options in the form.

Please note, you can specify that the new field appears on the same line as the previous field or object.

NUMBER and DATE fields can also be defined using the 'Edit Box' field type.

NUMBER FIELDS: In order to specify a range of values that can be allowed, for example 0.0 - 999.9, you would use the 'Response Should Be' option and fill in the min (>0.0) and max (<= 999.9) values as needed.

To specify a format mask for the number, use the 'For Number Field' option. For example, if you specify ###.## as the format mask, you must enter the number 1.2 as 001.2.

3. When you have completed designating the new field attributes, enter your e-signature and click submit.

H. Now you will notice the addition of your new date field. Please note the Field Name is what is displayed in your data entry form whereas Field ID is the corresponding name of the variable in the database.

Sequence	Field Name	Field ID	Field Type	Modify	Delete
Section 1					
Repeat Fields:0 Format: Non-Tabular					
(1)	Data Entry Date	er_def_date_01	Edit	Modify	Delete
(2)	Date of Visit	VISIT_DT	Edit	Modify	Delete

Use 'Preview' link to view the results as you add fields and work on the form layout.

I. Additional tools to complete your form creation are as follows:

Field Library Edit Box Multi Choice Copy Field Comment Lookup Line Break New Section Edit Section Datamap Space Break Form Link

1. **Edit Box:** choose text, number or date field
2. **Multiple Choice:** choose Drop down list (single response possible), Check Box (multiple responses allowed), or Radio Button (single response)
3. **Comment:** not a variable for data entry, this is a text box that can be used for labeling purposes in your form.
4. **Line Break:** not a variable for data entry, helpful for 'look and feel' organization of form layout.
5. **New Section:** you can divide your form into sections for organizational purposes
6. **Datamap:** IMPORTANT! Before your form is made active and thus ready for data entry, you may create your metadata table with this link. Metadata is exportable to excel for easy review.
7. **Space Break**:** used to control the vertical spacing in the form layout, its usage is well defined on [page 77 of the Velos Form Manual](#). (Accessible via the Velos Customer Corner)

Check mark/Date of Completion
Comments/ Notes

******The Space Break is a powerful tool used to refine the layout of the form. See the image below for details of how this tool can be utilized.

Image1: Form Preview of a Multiple Choice Field before adding a space break to move the yes/no responses closer together

Has the patient or authorized representative signed informed consent? ☐ Yes ←→ ☐ No

Date of Birth ?

Image2: Form Table with no space break in the No Repeat:Non-Tabular section

No Repeat: Non-Tabular	Repeat Fields:0	Format: Non-Tabular	
(1) Has the patient or author ...	demo_informed_consent	Multiple Choice	Modify
(2) Date of Birth	dob_mmddyyyy	Edit	Modify

Image3: Adding a Space break

FIELD TYPE: SPACE BREAK

Section*

Sequence*

Space Percentage* %

☒ Same line as previous field

Note the difference between Image1 vs. Image5. This is the result of putting a Space Break at 25% on the "Same line as previous field".

Image4: Form Table with a space break in the No Repeat: Non-Tabular section

No Repeat: Non-Tabular	Repeat Fields:0	Format: Non-Tabular	
(1) Has the patient or author ...	demo_informed_consent	Multiple Choice	Modify
(2) Space Break	-	Space Break	Modify
(3) Date of Birth	dob_mmddyyyy	Edit	Modify

Image5: Form Preview of a Multiple Choice Field after adding a space break

Has the patient or authorized representative signed informed consent? ☐ Yes ←→ ☐ No

Date of Birth ?

Source: Velos Form Manual, page 77.

J. Once you are satisfied with your form, finalize the form by updating the form status to 'Active'. To do this, go to the **Study Setup** tab, click on [Work in Progress](#) link in the Form Status column.

Summary Versions Admin Schedule **Study Setup** Notifications Study Status

Study Number: 26NOV07KW P

Associated Forms

Forms currently associated with this study are: [COPY AN EXISTING FORM](#) [DISPLAY AND SEQUENCING OPTIONS](#)

Name	Description	Linked To	Form Status
Additional Demographics	Additional Demographics	Patient	Work In Progress H

For each form, change Form Status to *Active* and submit:

Manage Protocols >> Associated Forms >> Form Status

Form Name : Blank

Please enter status details:

Form Status*

Form Start Date* [Select Date from Calendar](#)

Changed By* [Select User](#)

Notes

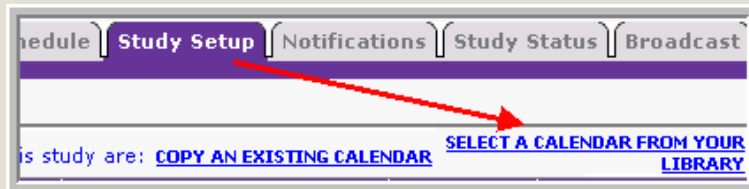
e-Signature*

**Check mark/Date of Completion
Comments/ Notes**



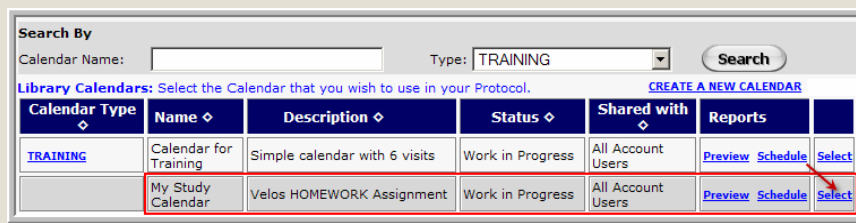
4. Copy a Basic Patient Study Calendar from the Calendar Library into your Study and modify appropriately:

- A. In the **Study Setup** tab, scroll **DOWN** to Associated Calendars; click on [SELECT A CALENDAR FROM YOUR LIBRARY](#) link.



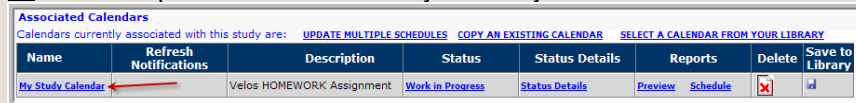
Check mark/Date of Completion
Comments/ Notes

- B. Search for and select 'My Study Calendar' in the Training category type. This provides a basic calendar template with 3 Visits which you can use for this particular study and evaluation.



Check mark/Date of Completion
Comments/ Notes

- C. Velos copies this calendar into your study as shown.



To view the details of the calendar, click on the calendar name as shown above.

Check mark/Date of Completion
Comments/ Notes

D. The details of the calendar are viewable and editable through three tabs: 'Define the Calendar', 'Select Events', 'Schedule and Customize' which comprises the 3 step wizard for calendar creation.

Check mark/Date of Completion
Comments/ Notes

Define the Calendar | Select Events | **Schedule and Customize**

Study Number: [Multi-Site Trial DEMO](#) Calendar: [My Study Calendar](#) Protocol Calendar Preview

Search By
Visit: Event:

Scheduled Events currently associated to this Calendar: [ADD VISIT\(S\)](#) [ADD EVENTS TO VISITS](#) [DELETE SELECTED](#)

Visit Name	Interval		Seq. No.	Category	Event	Visit Window	Select
Visit 1	Month 1, Week 1, Day 1	Copy visit					<input type="checkbox"/>
			(1)	Training	Clinic Event		<input type="checkbox"/>
			(2)	Training	Lab Event		<input type="checkbox"/>
Visit 2	Month 6, Week 1, Day 1	Copy visit					<input type="checkbox"/>
			(1)	Training	Clinic Event		<input type="checkbox"/>
			(2)	Training	Lab Event		<input type="checkbox"/>
Visit 3	Month 12, Week 1, Day 1	Copy visit					<input type="checkbox"/>
			(1)	Training	Clinic Event		<input type="checkbox"/>
			(2)	Training	Lab Event		<input type="checkbox"/>

NOTE: There can be multiple events for each visit.

To modify the visits or events in the calendar, click on the respective links under 'Visit Name' and 'Event'. Refer to the 'Velos eResearch 8.0 Calendar Manual' for details.



5. Link Patient forms (CRFs) to the Events in the Calendar

A. Under the 'Schedule and Customize' tab, click on the event name to access the event details screens.

Check mark/Date of Completion
Comments/ Notes

Define the Calendar | Select Events | **Schedule and Customize**

Study Number: [kwillson1](#) Calendar: [My Study Calendar](#)

Search By
Visit: Event:

Scheduled Events currently associated to this Calendar: [ADD VISIT\(S\)](#) [ADD EVENTS TO VISITS](#)

Visit Name	Interval		Seq. No.	Category	Event
V1 -- Baseline	Month 1, Week 1, Day 1	Copy visit			
			(1)	Training	Inclusion/Exclusion & Consent
			(2)	Training	Eligibility and Screening

B. Navigate to the 'CRF Details' tab :

Event Detail | Message | Cost | Appendix | Resource | **CRF Details**

Sequence * 1

Event Name * Clinic Event

Description null

CPT Code

Event Duration 1 Days

Visit Window 0 Days Before

0 Days After

Notes

Changes to Event Name and Description will not be applied to other events when you select 'Apply to all Events in this Visit'

☐ Apply to all Events in this Visit

☐ Apply to all **Clinic Event** Events in this Calendar

e-Signature *

Submit

Click once only

Check mark/Date of Completion
Comments/ Notes

C. Click on the 'Link Forms' and then select your active forms to be linked to the specific event:

Protocol Calendar [My Study Calendar] >> Event Crf

Event Name : Inclusion/Exclusion & Consent

No Records Present

Add CRF Link Forms

Associated Forms

Study Number: kwilson1

Protocol Calendar: My Study Calendar

Event: Inclusion/Exclusion & Consent

Forms Linked to Patients of this Study

Form Name	Select
Blank	<input type="checkbox"/>
CHILDHOOD TRAUMATIC Events Scale	<input type="checkbox"/>
CURRENT HEALTH ASSESSMENT	<input type="checkbox"/>
FAMILY HISTORY	<input type="checkbox"/>
FORMAL CARE & SERVICES QUESTIONNAIRE	<input type="checkbox"/>
INCLUSION CRITERIA	<input checked="" type="checkbox"/>
INFORMED CONSENT VERIFICATION	<input checked="" type="checkbox"/>

Scroll down to the bottom of the screen, where you can optionally link forms to all events in this visit, or link forms to all events in the calendar to save time.

☐ Apply to all Events in this Visit

☐ Apply to all Clinic Event Events in this Calendar

e-Signature *

Submit Close

Click once only

Enter your e-Signature and click on the 'Submit' button to save your work.

Velos verifies the inclusion of the forms linked to the event.

Protocol Calendar [My Study Calendar] >> Event Crf

Event Name : Inclusion/Exclusion & Consent

No Records Present Add CRF Link Forms

Associated Forms

Form Name

Forms Linked to Patients of this Study

INCLUSION CRITERIA
INFORMED CONSENT VERIFICATION

Repeat these steps 5.A through 5.C for linking the appropriate forms to the appropriate events in the calendar.

Check mark/Date of Completion
Comments/ Notes

6. Finalize the Calendar and change status to Active.

Please note that you can still link additional forms to your Calendar after the status is changed to Active.



A. Navigate to the 'Associated Calendars' section with the Study Setup Tab and click on the 'Work In Progress' link under the status column.

Summary Versions Admin Schedule **Study Setup** Notifications Study Status Reports Study Team Broadcast Forms

Study Number: kwilson1

Associated Calendars

Calendars currently associated with this study are:

Name	Refresh Notifications	Description	Status	Status Details
My Study Calendar		Velos HOMEWORK Assignment	Work in Progress	Status Details

UPDATE MULTIPLE SCHEDULES COPY AN EXISTING CALENDAR

Check mark/Date of Completion
Comments/ Notes

B. Select 'Active' from the dropdown box, complete the mandatory fields, enter your e-Signature and click on the 'Submit' button.

Summary Versions Admin Schedule **Study Setup** Notification

Study Number: kwilson1

Please change the Status

Protocol Calendar Name: My Study Calendar

Status: Active [What does this mean?](#)

Date *: 03/10/2010 [Select Date](#)

Status Changed By *: Kay Wilson [User Search](#)

Notes

e-Signature *:

Submit

Check mark/Date of Completion
Comments/ Notes



7. Update Study Status to 'Active.'

A. From the Study Setup tab, navigate to the Study Status tab. Click on the [ADD NEW STATUS](#) link.

Summary Versions Admin Schedule Study Setup Notifications **Study Status** Reports Study Team Broadcast Forms

Study Number: kwilson1

Search by Organization: All

Current Status	Study Start Date	Study End Date
Not Active		Change Dates

Study Status History:

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes
University of Michigan	Not Active	03/03/2010			

[ADD NEW STATUS](#)

B. Complete all mandatory fields in the Study Status screen, enter your e-Signature and click on the 'Submit' button.

Check mark/Date of Completion
Comments/ Notes

C. Notice the presence of the **P** icon when the current study status is 'Active/Enrolling.' The **P** icon provides a navigation link to enroll and manage patients on your study.

Check mark/Date of Completion
Comments/ Notes



8. Enroll Patients in your Study.

(Search for existing patients, register new patients, enroll registered patients.)

A. Click on the **P** icon and then the Patient Search tab.

A large patient pool has already been registered into the 'Training Organization' in UM Velos training database.

Check mark/Date of Completion
Comments/ Notes

B. Search for an existing patient by entering criteria such as first & last name, birth date, or CPI number in the Patient ID field. (The CPI number is the UM Hospital unique patient identifier.) In this example, training data is used.

Patient Search **Enrolled**

Enter CPI number as search criteria in the 'Patient ID' field.

Search By

Patient ID: Age: Organization:

Patient Name: Gender: Specialty:

Survival Status: Study: Provider: **Search**

Page 1 of 1 Rows per page Showing 1 - 1 of 1 [SAVE VIEW](#) [SAVE\(D\) SEARCH](#)

Patient ID	First Name	Last Name	Age	Gender	Patient Status	Other ID(s)	On a Study
005 001	Sigmond	Freud	54 Years	Male	Alive	View	Yes (1) AE SCH FORM

NOTE: In the UM Velos Production database, for patients affiliated with the UM organization, PATIENT ID is a unique number designated by the patient CPI number. Velos is a patient-centric database. This means that a unique patient and demographics data only needs to be entered once into Velos. It is extremely important not to add a patient into Velos that actually already exists. Duplicate patients will result in the need for a time-consuming technical intervention to correct, and always results in the need to re-enter data for that patient.

C. IF the patient you are looking for already exists and you have verified the CPI number, click on Patient ID link and select your study number from the drop-down list.

Patient Search **Enrolled**

Search By

Patient ID:

Patient Name:

Survival Status:

Page 1 of 1

Patient ID	First Name	Last Name
005 001	Sigmond	Freud

To screen / enroll an existing Velos patient into a new study, select the study and Patient organization from the drop-down box.

To screen/enroll this patient in a new study, select Study and Patient Organization: **Submit**

In the Patient Study Status window which pops-up, enter all mandatory data as designated by the red asterisks. Select 'Enrolled' from the Status drop-down list, and enter a Status Date.

Patient Study Status
Patient ID: 005 001 Study Number: kwilson1
Please enter Status details
Status * Enrolled
Reason Select an Option
Status Date * [Select Date](#)
☒ This is patient's current status in this study
Notes
Enrollment Details
Randomization Number
Enrolled By * Kay Wilson [Select User](#)
Additional Information
Patient Study ID * 005 001
Enrolling Site Training University

Check mark/Date of Completion
Comments/ Notes

Note that Patient Study ID is pre-populated with the CPI number. This number can be changed manually, after the patient is enrolled. However, if you had selected AUTO Generated, Velos would have populated this field with the format you specified.

D. IF patient/CPI number DOES NOT exist,

Manage Patients >> All Patients
Patient Search Enrolled
PATIENT ID 3609863490 AGE All
No patient found for your search criteria [Please modify the criteria and click on 'Search'.](#)

create a new patient, and REGISTER that patient to the Training University organization.

Check mark/Date of Completion
Comments/ Notes

Click on Manage Patients→New on the menu bar and enter data for the Patient Demographics form. This includes the Patient ID field, which at Michigan is always defined as the CPI number! Complete the data of birth field by clicking on the Calendar ICON and selecting a year, month, and date. Select Gender.

Then register the patient to the Training University organization (note: in the Production database it would be the University of Michigan) and designate survival status.

Finally, select your study to enter screening/enrollment details for this patient, enter your e-Signature, and click the 'Submit' button to save this data.

The screenshot shows the 'Manage Patients' interface. On the left is a navigation menu with 'Manage Patients' selected, and a sub-menu with 'New' highlighted. The main form contains the following fields and instructions:

- Patient ID ***: 001 001 (Red arrow points to this field with the note: "Always use CPI number for 'Patient ID.'")
- First Name**: Jake (Red arrow points to this field)
- Last Name**: Sulley (Red arrow points to this field)
- Date of Birth ***: 03/10/1988 (Red arrow points to the calendar icon)
- Gender**: Male (Red arrow points to the dropdown)
- Primary Ethnicity**: Non-Hispanic (Red arrow points to the dropdown)
- Primary Race**: White (Red arrow points to the dropdown)
- Registration Details**:
 - Organization ***: University of Michigan (Red arrow points to the dropdown)
 - Provider**: (Red arrow points to the 'Select User' link)
 - Survival Status ***: Alive (Red arrow points to the dropdown)
 - Cause of Death**: Select an Option (Red arrow points to the dropdown)
 - Patient Facility ID**: (Red arrow points to the field)
 - If Other**: (Red arrow points to the field)
 - Date of Death**: (Red arrow points to the calendar icon)
 - Specify Cause**: (Red arrow points to the field)
- Additional**: Two fields with 'SELECT' links (Red arrow points to the first 'SELECT' link)
- Specify groups/departments with access to edit patient's demographics. If blank, all groups have access**: (Red arrow points to the 'SELECT SPECIALTY' link)
- Select a study to enter screening/enrollment details for this patient:** kwilson1 (Red arrow points to the dropdown)
- e-Signature ***: (Red arrow points to the text input field)
- Submit**: (Red arrow points to the button with the note: "Click once only")

Other text on the page includes: "ALWAYS leave 'Specialty' BLANK!" and "Current User: Kay Wilson".

Note: If there are additional demographic fields required for capture, these would have to be captured on a form that you develop for your study.

In the Patient Study Status window which pops-up, enter all mandatory data as designated by the red asterisks. Select 'Enrolled' from the Status drop-down list, and enter a Status Date.

The screenshot shows the 'Patient Study Status' form. It contains the following fields and instructions:

- Patient ID:** 005 001
- Study Number:** kwilson1
- Please enter Status details**:
 - Status ***: Enrolled (Red arrow points to this dropdown)
 - Reason**: Select an Option (Red arrow points to the dropdown)
 - Status Date ***: (Red arrow points to the 'Select Date' link)
 - ☒ This is patient's current status in this study
 - Notes**: (Red arrow points to the text area)
- Enrollment Details**:
 - Randomization Number**: (Red arrow points to the field)
 - Enrolled By ***: Kay Wilson (Red arrow points to the 'Select User' link)
- Additional Information**:
 - Patient Study ID ***: 005 001 (Red arrow points to the field)
 - Enrolling Site**: Training University (Red arrow points to the dropdown)

**Check mark/Date of Completion
Comments/ Notes**

E. Repeat the patient search, Velos registration, and enrollment process until at least 3 patients have been enrolled in your study.



9. Link Your Enrolled Patients to the Study Calendar.

This links all forms in your study calendar to your patient. Therefore the Patient ID will automatically be associated with each form.

- A. From My Homepage, click on the **P** icon and then click on the patient study ID link of one of the patients whom you've enrolled in your study.

Check mark/Date of Completion
Comments/ Notes

- B. To link an enrolled patient to the study Calendar, click on the [Edit/Calendar/Date](#) link to select the protocol calendar in your study and designate a patient start date.

Check mark/Date of Completion
Comments/ Notes

Then, generate a patient schedule by completing/saving the following data entry screen:

Be sure to select a Date from the Calendar to designate this patient's DAY1 date, which is the date from which the entire schedule for this patient will be generated.

C. Upon submission of the form, Velos links the patient to the calendar and generates the patient schedule, as represented in the following screen:

Pat.ID: 005 001 Pat.Study ID: 005 001 Age: 54 years Gender: Male Pat.Name: Sigmond Freud Org: Training University

P SCREENING/ ENROLLMENT SCHEDULE ADVERSE EVENTS FORMS

Study #: kwilson1 View Title Calendar: My Study Calendar Pat.Start Date: 03/10/2010 Schedule: Current

Edit Calendar/Date View Previous Delete Schedule

Select Patient Schedule: My Study Calendar, 03/10/2010 Search

Visit: All Month/Year: All All Event: All Status: All

EDIT MULTIPLE EVENTS

Visit	Suggested Date	Scheduled Date	Visit Window	Events	Event Status	Linked Forms
March 2010						
V1 -- Baseline						ADD UNSCHEDULED EVENT
	03/10/2010	03/10/2010 C	-	Inclusion/Exclusion & Consent	Not Done C H	INCLUSION CRITERIA (No Response Entered) INFORMED CONSENT VERIFICATION (No Response Entered)
	03/10/2010	03/10/2010 C	-	Eligibility and Screening	Not Done C H	CHILDHOOD TRAUMATIC Events Scale (No Response Entered) CURRENT HEALTH ASSESSMENT (No Response Entered)
	03/10/2010	03/10/2010 C	-	Additional Demographics	Not Done C H	FAMILY HISTORY (No Response Entered)

From here, you can click on the Linked forms links and perform data entry. You can also Click on the Event status links to change the status of the events, as appropriate.

D. From the previous screen, click on the **P** icon and repeat these steps for all of the enrolled patients in your study. Select different start dates for each patient.

Check mark/Date of Completion
Comments/ Notes



10. Enter CRF data for your enrolled patients in your study.

A. Click on the **P** icon for your study, to access the patient enrollment roster; then click on the patient ID link.

Patient Search Enrolled

Search By

Patients on Study: kwilson1

Patient ID:

Patient Study ID:

Enter Screening/Enrollment details SELECT AN EX

Page 1 of 1

Study Number	Enrolling Site	Pt. Study ID	F Name	L Name
kwilson1	Training University	005 001	Sigmond	Freud

Check mark/Date of Completion
Comments/ Notes

B. Begin data entry by accessing the forms from the Form Links within the patient calendar:

Demographics | Patient Profile | **Protocols** | Reports | Appendix

Pat.ID: 005 001 Pat.Study ID: 005 001 Age: 54 years Gender: Male Pat.Name: Sigmond Freud Org: Training University

P SCREENING/ ENROLLMENT SCHEDULE ADVERSE EVENTS FORMS

Study #: [kwilson1](#) View Title Calendar: My Study Calendar Pat.Start Date: 03/10/2010 Schedule: Current

Edit Calendar/Date View Previous Delete Schedule

Select Patient Schedule: My Study Calendar, 03/10/2010 Search

Visit: All Month/Year: All All Event: All Status: All

Visit	Suggested Date	Scheduled Date	Visit Window	Events	Event Status	Linked Forms
March 2010						
V1 -- Baseline						ADD UNSCHEDULED EVENT
	03/10/2010	03/10/2010 C	-	Inclusion/Exclusion & Consent	Not Done C H	INCLUSION CRITERIA (No Response Entered) INFORMED CONSENT VERIFICATION (No Response Entered)
	03/10/2010	03/10/2010 C	-	Eligibility and Screening	Not Done C H	CHILDHOOD TRAUMATIC Events Scale (No Response Entered) CURRENT HEALTH ASSESSMENT (No Response Entered)
	03/10/2010	03/10/2010 C	-	Additional Demographics	Not Done C H	FAMILY HISTORY (No Response Entered)

C. Enter data on the form, update the form status to 'Completed', and save the data by submitting your e-Signature.

**Check mark/Date of Completion
Comments/ Notes**

D. Upon completing the last form within an event, Velos provides an opportunity to enter your e-Signature to mark the event as 'Done.'

Study #: [kwilson1](#) View Title Calendar: My Study Calendar Pat.Start Date: 03/10/2010 Schedule: Current

Edit Calendar/Date View Previous Delete Schedule

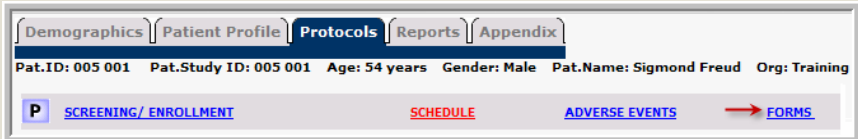


<https://velostraining.med.umich.edu/eres/jsp/promptMarkEventDone.jsp>

All CRF forms associated with this event have one or more responses added. Would you like to mark this event as 'Done'?

e-Signature * [Submit](#)
Click once only


Event Status	Linked Forms
	ADD UNSCH
Past Scheduled Date C H	INCLUSION CRITERIA Completed(1) INFORMED CONSENT VERIFICATION Completed(1)
Past Scheduled Date C H	CHILDHOOD TRAUMATIC Events Scale (No Response Entered) CURRENT HEALTH ASSESSMENT (No Response Entered)

Enter your e-Signature to change the event status to 'Done'. You can also close this box, click on the '[C](#)' in the Event status column to update the event status manually.

	<p>E. Perform data entry on at least several visits worth of forms for at least 2 of your patients to get a feel for how data entry is managed using a study calendar.</p> <p>Please note that it is not mandatory to use a calendar in your study. To enter patient data without using a calendar, access the patient forms via the 'Forms' link, as shown:</p>  <p>HOWEVER, if you <u>DO</u> use a patient calendar in your study, it is important to ALWAYS enter data via the form link within the patient schedule.</p> <p>[Do NOT mix data entry methods by sometimes entering data via the form link and sometimes entering data via the form link in the patient calendar. This practice will result in unwanted and confusing multiple records.]</p>	<p>Check mark/Date of Completion Comments/ Notes</p>
	<p>11. Explore a few patient management reports.</p> <p>For each report that you explore, export report results to excel and save the files to your computer. When you have completed this step, email the data reports to michr-support@umich.edu with your UNIQUE NAME / VELOS HOMEWORK in the subject line.</p>	
	<p>Generate Patient Management/Tracking Reports:</p>	
	<p>A. In your study, click on the P icon and click on a patient study ID link of the patient in your study for whom you have linked to a calendar <u>and</u> entered data.</p>	<p>Check mark/Date of Completion Comments/ Notes</p>
	<p>B. Click on the Reports tab.</p> 	<p>Check mark/Date of Completion Comments/ Notes</p>
	<p>C. Under All Patient Reports, Select Patient Form Tracking, enter appropriate filters, click the Display Report button, and export report to excel. Name the excel file STUDYNAME_Patient Form Tracking and save it to a folder on your computer.</p>	<p>Check mark/Date of Completion Comments/ Notes</p>
	<p>D. Under Patient Specific Reports, Select Patient Timeline, enter appropriate filters (select a patient who was linked to your study calendar), click the Display Report button, and export report to excel. Name the excel file STUDYNAME_Patient Timeline and save it to a folder on your computer.</p>	<p>Check mark/Date of Completion Comments/ Notes</p>
	<p>E. Under Patient Specific Reports, Select Patient Visit Calendar, enter appropriate filters (select a patient who was linked to your study calendar), click the Display Report button, and export report to excel. Name the excel file STUDYNAME_Patient Visit Calendar and save it to a folder on your computer.</p>	<p>Check mark/Date of Completion Comments/ Notes</p>

	<p>F. Under Study Specific Reports, Study Visit Calendar, enter appropriate date filters, Display Report, and export report to excel. Name the excel file STUDYNAME_Study Visit Calendar and save it to a folder on your computer.</p>	<p>Check mark/Date of Completion Comments/ Notes</p>
	<p>Email your excel output files of the 4 reports to: michr-support@umich.edu with your UNIQUE NAME / VELOS Training in the subject line.</p>	<p>Check mark/Date of Completion Comments/ Notes</p>

Please fax this page with your signature to: **734-998-7546, Attention: MICHR SUPPORT**

	<p>Record of COMPLETION</p> <p>Hands-on Training for New Users: Velos Study-Setup Procedures</p>
<p>PLEASE PRINT:</p> <hr/> <p>UNIQUE NAME</p> <hr/> <p>FIRST NAME LAST NAME</p>	<p>I have successfully completed the Velos Study Setup Procedures outlined in this reference guide using the UM Velos Training instance. I understand that it is my responsibility to keep up-to-date copies of my Velos training record, and pursue additional Velos training opportunities in the future.</p> <hr/> <p>DATE YOUR SIGNATURE</p>

The procedures outlined in this reference guide were to be conducted in conjunction with additional Velos training available on the Velos Customer Corner web site. Please include your Velos 'Record of Training Completion' with your application for an account in the UM Velos Production instance. These forms are available on the MICHR Velos web site: http://www.michr.umich.edu/programs/velos_training.html. Please FAX these signed/dated documents to MICHR Support (FAX: **734-998-7546**) or, scan and e-mail them to michr-support@umich.edu.

Thank you!